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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,039	07/12/2001	Shoulian Dong	3218.2A	3123

22886 7590 12/15/2004

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EXAMINER

KIM, YOUNG J

ART UNIT PAPER NUMBER

1637

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/904,039	<b>Applicant(s)</b> DONG ET AL.	
	<b>Examiner</b> Young J. Kim	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-53, 57 and 58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-53 is/are rejected.
- 7) ☒ Claim(s) 57 and 58 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/12/01; 3/24/03</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action responds the Amendment received on September 30, 2004.

#### ***Preliminary Remark***

All objections/rejections hereto not reiterated should be considered withdrawn.

#### ***Claim Objections***

Claim 39 is objected to because of the following informalities: in claim 39, the phrase, “reproducibly reducing the complexity...using a selected amplification method,” contains a comma followed by a semicolon, resulting from the current amendment. Comma should be deleted. Appropriate correction is required.

Claims 57 and 58 recite the phrase, “to remove single stranded DNA thereby obtaining only DNA duplexes.” However, the preceding method steps use a generic terminology of “nucleic acid” and “oligonucleotide,” which encompasses mRNA and RNAs, which would not result in a single strand DNA nor double stranded DNA (implied by the term, “DNA duplexes”).

#### ***Claim Rejections - 35 USC § 103 - Maintained***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The rejection of claims 39-53 under 35 U.S.C. 103(a) as being unpatentable over McCaskey (U.S. Patent No. 6,100,030, issued August 8, 2000, priority January 10, 1997) in view of DeRisi et al. (Science, October 1997, vol. 278, pages 680-686) and Moyer et al. (Applied and Environmental Microbiology, July 1996, vol. 62, no. 7, pages 2501-2507), made in the Office Action mailed on June 17, 2004 is maintained for the reasons of record.

Applicants' arguments received on September 30, 2004 have been fully considered but they are not found persuasive for the following reasons.

Applicants' arguments are addressed in the ordered they were presented.

Applicants state that claim 39 from which claims 40-53 depend have been amended to describe the relationship between the method of complexity reduction and the design of the array used to analyze the second nucleic acid sample" (page 6, Response) and that the combination of the selected fragmentation method and selected amplification method (*i.e.*, complexity reduction) results in a reproducible set of amplified fragments (page 7, 1<sup>st</sup> paragraph, Response).

As already set forth, McCaskey et al. already disclose such limitation.

As recited in the previous Office Action at page 6, the artisans disclose a method of detecting polymorphism in a nucleic acid sample by fragmenting genomic DNA, ligating adaptor sequences to the resulting fragments, wherein the adaptor sequences are complementary to the PCR primer sequences, amplifying the adaptor ligated fragments and hybridizing them to a microarray comprising an array of nucleic acids which are complementary to the amplified, adaptor-ligated fragments. Therefore, the implementation of the method of McCaskey et al. would necessarily result in a reproducible set of amplified fragments.

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Applicants argue that the array to which the nucleic acids are hybridized is, “designed to interrogate polymorphisms in samples subjected to the pre-selected complexity reduction method.”

Initially, the claims do not actively recite this limitation. The section of claim 39 which appears to contain this limitation is reproduced below:

“[P]roviding a nucleic acid array, wherein a computer system is used to identify polymorphisms that are predicted to be present on fragments that are amplified when the first nucleic acid sample is fragmented by said selected fragmentation method and amplified by said selected amplification method and wherein said array comprises probes to interrogate the genotype of a plurality of said polymorphisms...”

There is a disconnect between the limitation beginning with, “wherein a computer system is used...” and the array preceding the limitation because the wherein “clause” does not further modify the array. Rather, it requires that a computer be used to identify polymorphisms that are predicted to be present on fragments via selected fragmentation method and selected amplification method. However, even if, *arguendo*, that the array was designed via the above limitations, such limitation is considered to be an automation of a manual process in view of the motivation provided by McCaskey et al., wherein the artisans state:

“In one preferred embodiment, AFLP is used to identify differentially amplified nucleic acids, which are then converted into polynucleotide probes which map to polymorphisms. The differentially amplified AFLP DNAs are *converted into polynucleotide probes* by isolating individual polymorphic AFLP fragments from a mixture fragments in an AFLP amplification

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product, followed by using these isolated fragments as polynucleotide probes in *hybridization with immobilized DNA amplification mixtures*.

MPEP 2144.04(III), in discussing automation, states:

"In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958) (Appellant argued that claims to a permanent mold casting apparatus for molding trunk pistons were allowable over the prior art because the claimed invention combined "old permanent-mold structures together with a timer and solenoid which automatically actuates the known pressure valve system to release the inner core after a predetermined time has elapsed." The court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.)."

Since McCaskey et al. already demonstrates a manual activity in which to derive a probe, procedure in which computer is used to automate this procedure is considered to be obvious especially in view of the teachings of Moyer et al. who demonstrate that the use of computer simulation in predicting fragmented nucleic acid sequences has been established in the art at the time the instant invention was made.

Therefore, the invention as claimed is obvious over the cited references.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

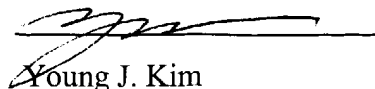
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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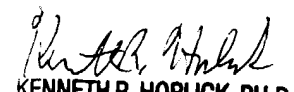
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### *Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim  
Patent Examiner  
Art Unit 1637  
12/8/04



KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

12/9/04

yjk